

No. 85-619

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Supreme Court, U.S.  
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IN THE

**Supreme Court of the United States**

OCTOBER TERM, 1985

MERRELL DOW PHARMACEUTICALS, INC.,

*Petitioner,*

v.

LARRY JAMES CHRISTOPHER THOMPSON and DONNA LYNN THOMPSON as Next Friends and Guardians of JESSICA ELIZABETH THOMPSON, LARRY JAMES CHRISTOPHER THOMPSON, Individually, and DONNA LYNN THOMPSON, Individually, *et al.*,

*Respondents.*

**BRIEF FOR RESPONDENTS**

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## QUESTIONS PRESENTED

1. Where a complaint founded on traditional theories of tort liability alleges that the defendant violated specific provisions of the Federal Food, Drug and Cosmetic Act and that the violation of the federal statute constitutes a rebuttable presumption of negligence, do such allegations arise under federal law so as to confer removal of jurisdiction on the district court?
2. Where a private litigant seeks a monetary remedy on the theory of negligence and alleges, *inter alia*, that a drug manufacturer violated provisions of the Federal Food, Drug and Cosmetic Act, do the allegations create a federal interest sufficient to require resolution by a federal court?

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**No. 85-619**

MERRELL DOW PHARMACEUTICALS, INC.,  
*Petitioner,*

vs.

LARRY JAMES CHRISTOPHER THOMPSON AND DONNA LYNN THOMPSON, AS NEXT FRIENDS AND GUARDIANS OF JESSICA ELIZABETH THOMPSON, LARRY JAMES CHRISTOPHER THOMPSON, INDIVIDUALLY, AND DONNA LYNN THOMPSON, INDIVIDUALLY, *et al.*

*Respondents.*

**On Writ of Certiorari to the  
United States Court of Appeals for the  
Sixth Circuit**

**BRIEF FOR RESPONDENTS**

**STATEMENT OF THE CASE**

Petitioner Merrell Dow Pharmaceuticals, Inc. (formerly known as Richardson-Merrell, Inc.) is a pharmaceutical manufacturer incorporated in Delaware with its principal place of business in Hamilton County, Ohio. The Respondents, Larry James Christopher Thompson and Donna Lynn Thompson, are Canadian citizens residing in Napanee, Ontario. The Respondents, Neil Frazier Mac-

Tavish and Margaret MacTavish, are British subjects residing in Linlithgow, Scotland. J.A. 17-18, 27-28.

The Thompsons and MacTavishes filed separate lawsuits against the Petitioner in the Court of Common Pleas, Hamilton County, Ohio, on September 1, 1983. They sued the Petitioner individually and as next friends and guardians of their minor children, Jessica Elizabeth Thompson and Neil MacTavish, respectively. The complaints in both actions virtually are identical with minor variations that are not pertinent to the instant appeal. Each complaint alleges that the minor child was born with multiple deformities as a result of the mother's ingestion of Bendectin, a drug product developed, tested, produced, manufactured and sold by Petitioner for the relief of nausea during pregnancy. J.A. 18, 28.

The allegations in each complaint are based on state-created theories of common law liability and grouped under six causes of action. The first three causes of action and the fifth and sixth causes of action, respectively, allege negligence, breach of warranties, strict liability in tort, common law fraud, and gross negligence. The fourth cause of action alleges that Petitioner violated specific reporting and labeling provisions of the Federal Food, Drug and Cosmetic Act (hereinafter FDCA), 21 U.S.C. § 301, *et seq.* (52 Stat. 1040), and that the violation of the federal statute in the promotion of Bendectin "constitutes a rebuttal presumption of negligence." J.A. 21-22, 31-32.

On September 8, 1983, Petitioner removed the cases from the Court of Common Pleas, pursuant to 28 U.S.C. § 1332 and 28 U.S.C. § 1441, on the grounds that the actions are "between citizens of a state and citizens or subjects of a foreign state, and [are] founded, in part, on an alleged claim arising under the laws of the United States." J.A. 36-37, 39-40.

On October 14, 1983, the Thompsons and MacTavishes filed a joint motion to remand under § 1447(c) and a memorandum in support thereof, J.A. 42-48. They noted that the Petitioner is a citizen of Ohio and, therefore, pursuant

to 28 U.S.C. § 1441(b), diversity of citizenship does not provide a basis for removal of the actions. J.A. 47. Addressing Petitioner's assertion that the actions arise under federal law, Respondents stated, in part:

In asking the Court to recognize the Food, Drug and Cosmetic Act as establishing the standard of care required of a drug manufacturer, federal jurisdiction is not vested in this Court under 28 U.S.C. § 1331. In the instant case, unlike *Cort v. Ash*, 422 U.S. 66 (1975) (private right of action principles set forth by Court), plaintiffs do not assert a federal statute as the jurisdictional basis for their claims, nor do they assert that their claims arise under the federal Food, Drug and Cosmetic Act.

\* \* \*

Plaintiff's actions, to be sure, do not arise under federal law, as they do not assert a federally-created cause of action. Plaintiffs only urge that the federal Food, Drug and Cosmetic Act embodies the appropriate *standard of care* to be employed by the Ohio Court in determining if Merrell has been negligent, or if Bendectin is a defective product.

J.A. 45-46.

Although the Thompsons and MacTavishes filed a joint motion to remand, they failed to include specific facts peculiar to the Thompsons in their memorandum in support of the motion. Under the heading, "Operative Facts," they state the following:

Plaintiffs are residents of Scotland, United Kingdom, who allege that their children suffered birth defects as the result of ingestion of Debendox during pregnancy. Debendox is the British trade

name for the antinauseant morning sickness drug Bendectin manufactured by defendant Merrell.

...  
J.A. 43.

The above statement pertains only to the MacTavishs. The Thompsons are citizens of Canada. The Canadian trade name for the drug product ingested by Donna Lynn Thompson is Bendectin. In their complaints, the Thompsons and MacTavishs refer to the drug product allegedly ingested as Benedectin. In fact, the trade name for the drug product ingested by Margaret MacTavish is Debendox. Respondents contend that Petitioner either developed, tested, promoted and/or manufactured the drug products ingested (both "Canadian" Bendectin and Debendox) in Hamilton County, Ohio, or directed these activities from Hamilton County, Ohio. Whether or not Petitioner performed or directed any or all of these activities is a factual dispute between the parties and is not properly before this Court in its consideration of the jurisdictional issue.

On October 31, 1983, Petitioner filed a memorandum in response to Respondents' motion to remand. J.A. 49-56. Petitioner stated, in part:

If Plaintiffs do not intend on litigating the issues concerning allegations that Merrell Dow violated the reporting requirements of the federal Food, Drug and Cosmetic Act in a state court action, then Merrell Dow concedes that, although clear from the face of the Complaints, no federal question jurisdiction exists in these cases.  
\*\*\*

Although Plaintiffs state that they are not suing to enforce the provisions of the federal Food, Drug and Cosmetic Act, they allege, nevertheless, that Merrell Dow violated provisions of the Act. "A suit may arise under federal law, even though a federal remedy is not sought, if the plaintiff's claim relies substantially on proposi-

tions that define federal rights, duties or relationships." *Guinasso v. Pacific First Federal Savings and Loan Assn.*, 656 F.2d 1364, 1367 n. 7 (9th Cir. 1981).

Based upon the foregoing citations of authority and upon Merrell Dow's suspicion that Plaintiffs will attempt to raise the alleged violations of a federal statute in the state court if the actions are remanded, it is submitted that this cause of action "arises under" the laws of the United States. . . .

J.A. 53, 55 (emphasis in original).

Respondents replied to Petitioner's memorandum in response on November 22, 1983. J.A. 57-60. They argued, in part, as follows:

The defendant is an Ohio corporation and the rights claimed are those of parents and children who seek redress under the common law for injuries sustained from the ingestion of defendant's drug product Bendectin (Debendox). The foundation of plaintiffs' lawsuit turns upon duties and responsibilities imposed upon defendant under the laws of negligence, strict liability, fraud and implied and express warranty.

\*\*\*

The mere reference to a federal statute as a criterion or test, when the law of the United States has no force of its own, does not suffice to establish that a cause of action arises under the laws of the United States. *Moore v. Chesapeake & Ohio Ry.*, 291 U.S. 205 (1934). . . .

\*\*\*

The validity, construction and/or effect of the Food, Drug and Cosmetic Act are not "pivotal" issues in this case; . . .

\*\*\*

Moreover, plaintiffs' assertions that defendant has violated the Food, Drug and Cosmetic Act also can be viewed as merely replies in anticipation that defendant will raise as defenses its compliance with the provisions of the Act and the subsequent approval of the Food and Drug Administration for the marketing of Bendectin. Again, a federal question is not embraced in this instance. *Phillips Petroleum Co. v. Texaco, Inc.*, 415 U.S. 125, 127-28 (1974).

J.A. 57-59 (emphasis in original).

While Respondents' motion to remand was pending, Petitioner moved to dismiss Respondents' actions on the ground of *forum non conveniens*. In one opinion, filed May 14, 1984, the District Court denied Respondents' motion to remand and granted Petitioner's motion to dismiss the case on the ground of *forum non conveniens*. J.A. 13-16. In its consideration of the jurisdictional issue, the district court noted that "[i]n attempting to clarify the phrase 'arising under,' the Supreme Court has formulated definitions employing varying language. . . ." (citations omitted). J.A. 14-15. By way of a footnote, the district court stated that Respondents' cases are analogous to *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180 (1921), and distinguishable from *Moore v. Chesapeake & Ohio Ry.*, 291 U.S. 205 (1934). J.A. 15 n. 3. On that premise, the District Court applied the general rule set forth in *Smith* to Respondents' fourth causes of action. The district court stated:

Phrased in terms of the *Smith* standard, plaintiffs' "right to relief depends upon the . . . application of the . . . laws of the United States." *Smith, supra*, at 199. Accordingly, the Court holds that plaintiffs' fourth cause of action arises

under the laws of the United States and that these cases were properly removed . . . .

J.A. 15-16.

On appeal, Respondents argued only the jurisdictional issue. The court of appeals reversed the judgment of the district court on jurisdictional grounds and remanded Respondents' action to the district court with instructions to remand the actions to state court. J.A. 8-10. The court of appeals stated:

The standard for determining when an action is removable is whether the court would have had jurisdiction, subject to the limitations of § 1441(b), if the action had been instituted originally in federal court under 28 U.S.C. [sic] §1331 or § 1332. See *Franchise Tax Board v. Construction Laborers Vacation Trust*, 103 S.Ct. 2841, 2845 (1983). Consequently, a case removed to federal court under the guise of federal question jurisdiction presents a federal question when it "arises under" federal law. In *Franchise Tax Board*, the Court stated:

Under our interpretations, Congress has given the lower courts jurisdiction to hear, originally or by removal from a state court, only those cases in which a well pleaded complaint establishes either that federal law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law.

*Id.* at 2856 [463 U.S. at 27-28].

The parties agree that the FDCA does not create or imply a private right of action for individuals injured as a result of violations of the Act. Federal question jurisdiction would, thus, exist only if plaintiffs' right to relief depended necessarily on a substantial question of federal law. Plaintiffs' causes of action referred to the FDCA merely as

one available criterion for determining whether Merrell Dow was negligent. Because the jury could find negligence on the part of Merrell Dow without finding a violation of the FDCA, the plaintiffs' causes of action did not depend necessarily upon a question of federal law. Consequently, the causes of action did not arise under federal law and, therefore, were improperly removed to federal court. *See Zeig v. Shearson/American Express, Inc.*, 592 F.Supp. 612, 613-14 (E.D.Va. 1984); *State of Florida ex rel. Broward County*, 329 F.Supp. 364, 366 n. 3 (S.D.Fla. 1971).

J.A. 9-10.

Petitioner filed a petition for a writ of *certiorari* which was granted on December 2, 1985.

### SUMMARY OF ARGUMENT

Respondents' allegations of negligence based on violation of the FDCA are not created by federal law. Federal courts that have considered claims alleging violation of the Act have uniformly refused to imply a private right of action under the Act on the basis that Congress expressly determined that a federal right of action under the Act would unnecessarily duplicate available state remedies. Moreover, Respondents' claims cannot be considered as disguised attempts to state claims directly under the Act, for Respondents specifically allege that violation of the federal statute "constitutes a rebuttable presumption of negligence." Respondents' claims are, therefore, state-created claims predicated on the theory of negligence.

The court of appeals correctly found that plaintiffs' right to relief on the theory of negligence does not necessarily depend on a substantial question of federal law. In applying the test set forth in *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1 (1983), this Court properly recognized that violation of the federal statute was merely an alternative ground on which neg-

ligence could be predicated and, therefore, Respondents could obtain relief on the theory of negligence without a finding that the statute was violated. The court of appeals' treatment of Respondents' fourth causes of action is consistent with the treatment of other courts considering the availability of federal question jurisdiction over complaints containing several separately numbered "counts," or "causes of action," founded on negligence, one of which alleges violation of a federal statute. Although the claims of negligence are alleged in separate counts or causes of action, these courts have emphasized that the gravamen of the claims is negligence and that each claim merely alleges another ground for negligence. This approach is based on practicality and necessity. Moreover, it is consistent with this Court's statements that a cause of action consists of a *right* which the facts merely show and, therefore, multiplication of the grounds of negligence alleged to have caused the same injury does not multiply the causes of action. Neither the holding nor the approach of the Court in *Franchise Tax Board* foreclose analysis of each "cause of action" in terms of its underlying legal basis which the separately alleged facts show, in order to determine the "whole" cause of action *before* applying the *Franchise Tax Board* test. In fact, in *Franchise Tax Board*, the plaintiff's action for a declaratory judgment presented federal questions on its face and the plaintiff's right to the declaration sought necessarily depended on resolution of the questions. Nonetheless, the Court analyzed the declaratory cause of action in terms of the underlying coercive action before applying its own test.

This Court has specifically held that state law negligence claims invoking federal safety statutes do not create federal question jurisdiction. *Moore v. Chesapeake & Ohio Ry.*, 291 U. S. 205 (1934). Analysis of the *Moore* opinion, in conjunction with other opinions that examine these claims, reveals that the effect of a violation of the statute in the resolution of the claim is decided by the state court on common law principles or by statute and, hence, will vary according to the jurisdiction. Moreover, these claims pre-

sent state issues bearing on a plaintiff's right to recover, such as proximate cause and contributory negligence, that predominate over any concerns over the application of a federal statute. The Court's holding in *Moore*, therefore, is based on the reality that the states' interest in resolving these claims overshadows any federal interest. It follows that the reference to a federal statute in Respondents' fourth causes of action is not sufficient to warrant primary adjudication in the federal courts. As this Court stated in *Moore*, any questions concerning the application of a federal statute that may arise may be appropriately reviewed by this Court on *certiorari*.

Respondents' allegations of negligence based on violation of the FDCA function as assertions that federal law deprives Petitioner of a defense or defenses he may raise and, therefore, do not give rise to federal question jurisdiction. The effect of violations of the FDCA in the instant case is determined by the common law of Ohio. However, if violation of the statute is negligence *per se* under Ohio law, then Respondents' allegations deprive Petitioner of any defenses to a claim of negligence under Ohio law. If, on the other hand, violation of the statute constitutes a rebuttable presumption of negligence, then Respondents' allegations foreclose the defense that negligence was not shown by a preponderance of the evidence. If violation of the statute is considered only evidence of negligence, then Respondents' allegations deprive Petitioner of the defense that it met the standard of care of the reasonable drug manufacturer.

Congress has established that the provisions of the FDCA are to be enforced publicly, and federal courts have refused to imply a private right of action under the Act. Resolution of claims involving only private litigants by a federal court, therefore, will not promote the federal scheme regulating pharmaceuticals, nor will application of provisions of the FDCA by the Ohio court to a private claim burden the United States in its enforcement of the Act. The allegations in Respondents' fourth causes of action rely on well-defined provisions that can be applied

by the Ohio court. Moreover, the foreign citizenship of Respondents raises only disputed factual issues regarding whether Petitioner developed, tested, promoted, manufactured, or sold Bendectin (Debendox) in Ohio or directed any of these activities from Ohio. Respondents' fourth causes of action simply do not create a federal interest sufficient to warrant invoking the jurisdiction of the federal court.

Finally, any finding that state law negligence claims alleging violation of a federal safety statute give rise to federal question jurisdiction will provide every plaintiff suing a party subject to federal regulation with an opportunity to invoke federal jurisdiction. Similarly, defendants regulated by federal statutes arguably would be able to remove these claims to federal court, if the plaintiff alleges that a defendant failed to follow safety precautions required under a federal statute, but does not specifically refer to the statute. In either event, there would be an untenable flood of tort litigation in the federal courts, which Respondents submit is most appropriately left to the state courts under 28 U.S.C. § 1331.

#### ARGUMENT

**I. WHERE A COMPLAINT FOUNDED ON TRADITIONAL THEORIES OF TORT LIABILITY ALLEGES THAT THE DEFENDANT VIOLATED SPECIFIC PROVISIONS OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT AND THAT THE VIOLATION OF THE FEDERAL STATUTE CONSTITUTES A REBUTTABLE PRESUMPTION OF NEGLIGENCE, SUCH ALLEGATIONS DO NOT ARISE UNDER FEDERAL LAW SO AS TO CONFER REMOVAL JURISDICTION ON THE DISTRICT COURT.**

**A. The Court of Appeals Correctly Found That Federal Law Does Not Create Respondents' Fourth Causes Of Action Nor Does Respondents' Right To Relief Necessarily Depend On Resolution Of A Substantial Question Of Federal Law And, Therefore, Respondents' Complaints Do Not Present A Federal Question Upon Which Removal Properly Could Be Based.**

The right of removal is a congressionally-imposed restriction on the power of a state court to determine controversies and, therefore, the removal statutes must be strictly construed. *Shamrock Oil & Gas Co. v. Sheets*, 313 U.S. 100, 108-109 (1941). If, prior to judgment, it appears that an action was improperly removed from state court, the district court must remand it to the state court. 28 U.S.C. § 1441(c); *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1, 8 (1983). When the defendant is a citizen of the state in which the action is brought, the propriety of removal depends on whether the case is within the original jurisdiction of the federal courts under 28 U.S.C. § 1331. *Id.* at 8.<sup>1</sup>

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<sup>1</sup>28 U.S.C. § 1441 provides:

(a) Except as otherwise expressly provided by Act of Congress, any civil action brought in a State Court of which the district courts of the United States have original jurisdiction, may be removed by the defendant or the defendants, to the district court of the United States for the district and division embracing the place where such action is pending.

(b) Any civil action of which the district courts have original jurisdiction founded on a claim or right arising under the Constitution, treaties or laws of the United States shall be removable without regard to the citizenship or residence of the parties. Any other such action shall be removable only if none of the parties in interest properly joined and served as defendants is a citizen of the State in which such action is brought.

(c) Whenever a separate and independent claim or cause of action, which would be removable if sued upon alone, is joined with one or more otherwise non-removable claims or causes of action, the entire case may be removed and the district court may determine all issues therein, or, in its discretion, may remand all matters not otherwise within its original jurisdiction.

Section 1331 provides that "the district courts shall have orig-

In *Franchise Tax Board*, the Court cautioned that "the statutory phrase 'arising under the Constitution, laws, or treaties of the United States' has resisted all attempts to frame a single, precise definition for determining which cases fall within, and which cases fall outside, the original jurisdiction of the district courts." *Id.* at 8. However, after considering the various definitions formulated in the past, the Court set forth the following two-pronged test:

Under our interpretations, Congress has given the lower federal courts jurisdiction to hear, originally or by removal from a state court, only those cases in which a well-pleaded complaint established either that *federal law creates the cause of action* or that *the plaintiffs' right to relief necessarily depends on resolution of a substantial question of federal law*.

*Id.* at 27-28 (emphasis added).

**1. Respondents' allegations, although invoking a federal safety statute, constitute a claim of right under Ohio law.**

The Federal Food, Drug and Cosmetic Act (FDCA) does not expressly create a private right of action, and federal courts have uniformly refused to imply a private right of action under the Act. *Pacific Trading Company v. Wilson & Co., Inc.*, 547 F.2d 367 (7th Cir. 1976); *National Women's Health Network, Inc. v. A. H. Robins, Inc.*, 545 F.Supp. 1177 (D.Mass. 1982); *Gelley v. Astra Pharmaceutical Products, Inc.*, 466 F.Supp. 182 (D.Minn. 1979), aff'd, 610 F.2d 558 (8th Cir. 1979); *State of Florida ex. rel. Broward County v. Eli Lilly & Co.*, 329 F.Supp. 364 (S.D.Fla. 1971); *Cross v. Board of Supervisors of San Mateo County*, 326

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inal jurisdiction of all civil actions arising under the Constitution, treaties or laws of the United States." 28 U.S.C. § 1331 (1976 ed. Supp. V).

F.Supp. 634 (N.D.Cal. 1968), *aff'd*, 442 F.2d 362 (9th Cir. 1971).<sup>2</sup>

Petitioner submits, nevertheless, that Respondents' fourth causes of action are a disguised attempt to state a claim directly under the FDCA. In order to support its position, Petitioner urges that Court to ignore Respondent's specific allegation that violation of the federal statute constitutes a rebuttable presumption of negligence. Relying on *Bell v. Hood*, 327 U.S. 678 (1946), Petitioner asserts that the district court had subject matter jurisdiction to determine whether Respondents' fourth causes of action state a claim upon which relief can be granted.

Respondents' fourth causes of action are specifically predicated on a state law theory of negligence. This allegation of negligence cannot be ignored in examining the basis for their claim. The petitioners in *Bell* filed suit directly in federal district court to recover damages allegedly sustained as a result of a violation of their rights under the Fourth and Fifth Amendments. The complaint in *Bell* contained no allegations predicated plaintiffs' claim on a common law theory of tort liability made actionable by state law.

In contrast, Respondents herein filed their actions in state court. Although they invoke a federal safety statute in their fourth causes of action, they allege that the violation of the statute gives rise to liability pursuant to the common law theory of negligence. Moreover, the FDCA does not provide a right of action to individuals injured

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<sup>2</sup>Applying the standards for determining the availability of an implied right of action as set forth in *Cort v. Ash*, 422 U.S. 55 (1975), courts have examined the legislative history of the FDCA. An express provision for a private right of action for damages was included in an early version of the FDCA, but omitted from all later versions on the ground that it would create unnecessary federal action duplicative of state remedies. *National Women's Health Network, Inc. v. A. H. Robins, Inc.*, 545 F.Supp. at 1179-80; *State of Florida ex rel. Broward County*, 329 F.Supp. at 365.

as a result of violations of the Act, nor do Respondents attempt to state a claim under the Act. Federal law, therefore, does not create Respondents' fourth causes of action and Petitioner's reliance upon *Bell* is misplaced.

**2. Respondents' right to relief does not necessarily depend on resolution of an issue of federal law.**

The fact that an issue of federal law may or will emerge during the course of litigation is not sufficient to establish federal question jurisdiction. *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1, 27-28 (1983); *Gully v. First Nat. Bank in Meridian*, 299 U.S. 109, 115 (1936) ("A genuine and present controversy, not merely a possible or conjectural one, must exist with reference thereto. . . ."). *Id.* at 113 (citations omitted). In *Shulthis v. McDougal*, 225 U.S. 561 (1911), the Court stated:

A suit to enforce a right which takes its origin in the laws of the United States is not necessarily, or for that reason alone, one arising under those laws, for a suit does not so arise unless it really and substantially involves a dispute or controversy respecting the validity, construction, or effect of such a law, *upon the determination of which the result depends*.

*Id.* at 569 (emphasis added).

Similarly, under the rule set forth in *Franchise Tax Board*, federal courts have jurisdiction over cases which present state created causes of action only if "a well-pleaded complaint establishes . . . that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law." 463 U.S. at 27-28. Applying the *Franchise Tax Board* test, the court of appeals in the instant case found that Respondents' right to relief on the theory of negligence does not necessarily depend on resolution of an issue of federal law. The court of appeals reasoned that Respondents rely on the FDCA as one available criterion or test which the Ohio court could apply in determining whether Petitioner was negligent and, there-

fore, Petitioner could be found negligent without resolving the federal issue.

This rationale is consistent with this Court's statement in *Gully*:

[A] finding upon evidence that the Mississippi law has been obeyed may compose the controversy altogether, leaving no room for a contention that the federal law has been infringed. The most one can say is that a question of federal law is lurking in the background, . . . .

299 U.S. at 117.

Petitioner misconstrues the nature of Respondents' complaints and, in particular, their fourth causes of action, in asserting that the court of appeals misapplied the *Franchise Tax Board* test by treating Respondents' first and fourth causes of action collectively. Other federal courts considering complaints that allege general negligence in one count, or cause of action, and negligence based on violation of a federal statute in another count, or cause of action, have recognized that the legal basis for the relief sought is the same in both counts, namely, negligence. See *Owens v. New York Central Railroad Co.*, 267 F.Supp. 252 (E.D.Ill. 1967); *Boncek v. Pennsylvania R. Co.*, 105 F.Supp. 700 (D.N.J. 1952).

In *Owens*, plaintiff's complaint consisted of seven counts or causes of action. Counts I, III, V, VI and VII were based on general negligence and breach of warranty. Counts II and IV alleged negligence based on violation of the Safety Appliance Act, particularly 45 U.S.C. § 2. *Id.* at 253. The defendants removed the case to district court on the ground that it arose under the federal law. The plaintiff moved for remand and the district court granted the motion. In reviewing the legal bases of the complaint, the court stated:

Considering the complaint in its entirety and each count separately, the basis upon which the action is founded is negligence or breach of warranty;

and it makes no difference whether the negligence pleaded is founded on common law principles or upon the violation of state or federal statute, still the gist of the action is negligence.

The gravaman [sic] of the cause of action stated in Counts II and IV is negligence and, the cause of action being based on negligence, the alleged violation of the statute is merely one of the props utilized here to support the negligence allegations. *That one of the props is the alleged violation of a federal statute does not remove the cause of action from the realm of negligence.* . . . .

*Id.* at 255 (emphasis added).

*Boncek v. Pennsylvania R. Co.* involved numerous actions against multiple defendants for damages resulting from an explosion of munitions. The complaints in certain of the actions contained six counts. The first count alleged general negligence and the fifth count alleged negligence based on violation of the applicable statutes and regulations of the United States, the State of New Jersey and the City of South Amboy, New Jersey. *Id.* at 702. The fifth count specifically identified the regulations of the United States Coast Guard, 46 C.F.R. §§ 142-146, inclusive, and 49 C.F.R. § 73, as well as a New Jersey statute and a city ordinance. *Id.* at 705. The defendants removed the cases and plaintiffs moved to remand. Addressing the issue of federal question jurisdiction, the court stated:

The gravamen of the claims in these suits is that the negligence of the defendants caused the explosion which resulted in damage to the plaintiffs. It is true that one of the charges of negligence embraces a failure to comply with federal statutes and regulations prescribed for the handling, transportation, etc. of explosives. But no recovery is sought under and by virtue of the terms of any federal statutes or regulations. The right of action for the breach of such duty (if we assume that Congress by such statutes and regu-

lations prescribed absolute duties and created correlative rights in favor of injured persons) was created by and enforceable under the laws of the State of New Jersey, and does not really and substantially involve a controversy respecting the validity or construction of a law of the United States *upon the determination of which the result depends.* . . .

*Id.* at 706 (emphasis added).

The second prong of the *Franchise Tax Board* test encompasses the general rule enumerated in *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180 (1920), which the district court applied in ruling on Respondents' motion to remand. In *Smith*, plaintiff brought a suit in federal court to enjoin a trust company from investing its funds in farm loan bonds issued by federal land banks or joint stock land banks under the authority of the Federal Farm Loan Act of July 17, 1916, as amended. The sole basis for seeking the injunction was that the Federal Acts were unconstitutional and void. In its examination of the jurisdictional issue, this Court stated:

The bill prays that the acts of Congress authorizing the creation of the banks, especially sections 26 and 27 thereof, shall be adjudged and decreed to be unconstitutional, void and of no effect, and that the issuance of the farm loan bonds, and the taxation exemption feature thereof, shall be adjudged and decreed to be invalid.

\* \* \*

The company is authorized to invest its funds in legal securities only. The attack upon the proposed investment in the bonds described is because of the alleged unconstitutionality of the acts of Congress undertaking to organize the banks and authorize the issue of the bonds. *No other reason is set forth in the bill as a ground of*

*objection to the proposed investment* by the board of directors acting in the company's behalf. . . .

\* \* \*

The general rule is that, where it appears from the bill or statement of the plaintiff that the right to relief depends upon the construction or application of the Constitution or laws of the United States, and that such federal claim is not merely colorable, and rests upon a reasonable foundation, the District Court has jurisdiction under this provision.

\* \* \*

The objecting shareholder avers in the bill that the securities were issued under an unconstitutional law, and hence of no validity. *It is therefore apparent that the controversy concerns the constitutional validity of an act of Congress which is directly drawn in question. The decision depends upon the determination of this issue.*

*Id.* at 198-201 (emphasis added).

Smith could not succeed in his suit to enjoin the banks without a declaration that the Federal Act was unconstitutional. He pled no alternative ground on which an injunction could issue. His right to relief, therefore, depended on the construction of federal law. In contrast, Respondents have alleged alternative bases on which Petitioner could be found negligent. Although specific provisions of the FDCA may, or even will, be used as a standard of care for determining negligence, Respondents' right to relief under the theory of negligence *does not depend on* application of the provisions.

Other courts also have reached similar conclusions in assessing the effect of allegations of statutory violations in determining federal question jurisdiction. In *Guthrie v. Alabama By-Products Co.*, 328 F.Supp. 1140 (N.D.Ala.

1971), *aff'd per curiam*, 456 F.2d 1294 (5th Cir. 1972), cert. den., 410 U.S. 946 (1973), reh. den., 411 U.S. 910 (1973) lower riparian landowners sued industrial corporations in federal court for damages and injunctive relief for alleged water pollution. The original complaint alleged federal question jurisdiction on the theory that defendants were depositing refuse in navigable waters in violation of section 13 of the Rivers and Harbors Appropriation Act of 1899, 33 U.S.C. § 407. In addition, the plaintiffs alleged liability for the same acts under common law theories of negligence, trespass and nuisance. The defendants moved to dismiss for lack of subject matter jurisdiction. The plaintiffs, thereupon, filed amendments to the complaint which, *inter alia*, urged pendant jurisdiction of their non-federal claims and divided their claims into six separate counts. One count asserted claims based upon violations of 33 U.S.C. § 407. The other counts alleged negligence, willful and wanton misconduct, nuisance and deprivation of property in violation of 42 U.S.C. § 1983 and the Fifth and Fourteenth Amendments. *Id.* at 1442.

In determining the availability of federal question jurisdiction for the alleged violation of 33 U.S.C. § 407 (Rivers and Harbors Appropriation Act), the court examined the legislative history of the Act and concluded that a private right of action could not be implied under the Act. In addition, the court stated:

*First, it is clear that the plaintiffs' right to relief does not depend exclusively upon the existence of 33 U.S.C.A. § 407, or upon whether the defendants are violating that statute. The law of Alabama recognizes a right of action for past damages, as well as a right to injunctive relief to prevent future damages, for impairment of the value and enjoyment of riparian lands resulting from water pollution....*

*Id.* at 1144 (emphasis added).

The court, therefore, concluded (1) that the Act did not create a cause of action for individuals damaged as a result of violations of the Act and (2) that the plaintiffs' right to relief did not necessarily depend on whether there was a violation of the Act and held that federal jurisdiction was not available.

In *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1 (1983), the plaintiff filed a complaint in state court, alleging two causes of action. The first cause of action sought damages for defendants' failure to comply with tax levies issued under state law. The second cause of action sought a declaration that the defendants were legally obligated to honor all future levies on the ground that the defendants contended that section 514 of the Employment Retirement Income Security Act (ERISA) of 1974, 88 Stat. 829, 29 U.S.C. § 1001, *et seq.*, preempts state law and that the defendants lack the power to honor the levies. The defendants removed the case to federal court, and the plaintiff moved for remand. The district court denied the motion. An appeal was taken ultimately to this Court, which held that the case was improperly removed.

After discussing the various rules articulated in the past for determining the availability of federal question jurisdiction, this Court stated:

Simply to state these principles is not to apply them to the case at hand. Appellant's complaint sets forth two "causes of action," one of which expressly refers to ERISA; if either comes within the original jurisdiction of the federal courts, removal was proper as to the whole case.

*Id.* at 13.

The Court's statement does not dictate that a lower federal court should not consider the basis of a plaintiff's right to relief in each cause of action before determining whether a particular cause of action arises under federal law. In *Franchise Tax Board*, the causes of action sought two types of relief. The first sought coercive relief, whereas

the second sought declaratory relief. As to the second cause of action, the Court stated:

Not only does appellant's request for a declaratory judgment under California law clearly encompass questions governed by ERISA, but appellant's complaint identifies no other questions as a subject of controversy between the parties. Such questions must be raised in a well-pleaded complaint for a declaratory judgment. Therefore, it is clear on the face of its well-pleaded complaint that appellant may not obtain the relief it seeks in its second cause of action . . . without a construction of ERISA and/or an adjudication of its pre-emptive effect and constitutionality—all questions of federal law.

*Id.* at 14 (footnote omitted). Although the questions governed by ERISA appeared on the face of the plaintiff's fourth cause of action and the relief sought required a construction of ERISA, the Court found that the cause of action did not arise under federal law. The Court looked beyond the request for declaratory relief to the underlying coercive action that might be brought absent the availability of declaratory relief, and determined that the plaintiff's right to coercive relief did not depend on a construction of ERISA.

In the instant case, the court of appeals analyzed Respondents' fourth cause of action "with an eye to practicality and necessity." *Id.* at 20. It recognized that the common predicate or basis of Respondents' first and fourth causes of action was the state law theory of negligence, and determined that Respondents' right to relief under that theory did not depend on resolving the federal issue. The court of appeals' collective treatment of Respondents' first and fourth causes of action is consistent with this Court's statement in *Baltimore S.S. Co. v. Phillips*, 274 U.S. 316, 321 (1926):

A cause of action does not consist of facts, but of the unlawful violation of a *right* which the

facts show. The number and variety of the facts alleged do not establish more than one cause of action so long as their result, whether they be considered severally or in combination, is the violation of but one right by a single legal wrong. *The mere multiplication of grounds of negligence alleged as causing the same injury does not result in multiplying the causes of action.* "The facts are merely the means, and not the end. They do not constitute the cause of action, but they show its existence by making the wrong appear."

*Id.* at 321 (citation omitted) (emphasis added).

Petitioner's reliance on *United Mine Workers v. Gibbs*, 383 U.S. 715 (1966), in attempting to establish what the *Franchise Tax Board* Court meant by cause of action, is misplaced. In effect, Petitioner puts the cart before the horse in its analysis, by initially presupposing that Respondents' first and fourth causes of action state separate claims, one state and one *federal*. However, both the first and fourth causes of action in Respondents' complaints are state-created, as Petitioner clearly admits. Petitioner's Brief at p. 10.

In *Gibbs*, plaintiff brought suit in federal court for damages, alleging that he lost his job and trucking contracts as a result of the activities of the defendant in a violent labor dispute. His complaint alleged violations of section 303 of the Labor Management Relations Act, 1947, 61 Stat. 158, as amended, and the common law of Tennessee. Jurisdiction was premised on allegations of secondary boycotts under section 303, which provides for a private right of action for any individual injured in his property or business as a result of secondary boycotts. The complaint in *Gibbs* sought relief directly under section 303. If the facts alleged in the complaint had constituted secondary boycotts, *Gibbs* would have had a right to relief under section 303. Thus, *Gibbs'* claim of secondary boycotts under section 303 was a *federal* claim. Because it was a federal claim vesting subject matter jurisdiction in the district

court, the district court had pendent jurisdiction to hear Gibbs' state claim.

Only *after* one of several causes of action is determined to create federal question jurisdiction does the power of pendent jurisdiction vest. If a claim is state-created, the second prong of the *Franchise Tax Board* test must be applied *before* making a determination that federal question jurisdiction exists. The holding in *Gibbs* does not foreclose analysis of a state-created "cause of action" in terms of the legal theory on which it is predicated before applying the *Franchise Tax Board* test. As previously noted, the Court in *Franchise Tax Board* analyzed the plaintiff's second cause of action for declaratory relief "with an eye to practicality and necessity," before applying its own test.

As the court of appeals noted at the outset of its inquiry, the propriety of removal turns upon whether federal question jurisdiction would exist if the actions were originally brought in federal court. J.A. 9. In light of Congress' express refusal to provide a private right of action under the FDCA because it would duplicate available state remedies,<sup>3</sup> it would appear illogical that a federal court would have original jurisdiction over Respondents' allegations of violation of the FDCA merely because they were alleged under a separate "cause of action" as an alternative ground for relief under the common law theory of negligence.

**B. A Claim That Alleges A Common Law Theory Of Negligence Based On The Violation Of A Duty Imposed By A Federal Penal Statute Does Not Constitute An Independent Basis For Federal Jurisdiction.**

The courts of various states have created, on common law principles, or by statute, liability for breach of a state or federal penal statute, when the breach results in injury of the kind the statute was intended to prevent. If the claim invokes the provisions of a federal safety statute pursuant to the state-created theory of liability, a reference to a federal statute necessarily will appear on the

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<sup>3</sup>See fn. 2, *supra*.

face of the complaint. Nonetheless, this Court and lower federal courts have consistently stated that such claims do not vest subject matter jurisdiction in a federal court when diversity of citizenship is absent.

This Court specifically addressed the issue of whether state-created claims based on violation of a federal safety statute give rise to federal question jurisdiction in *Moore v. Chesapeake & O. Ry. Co.*, 291 U.S. 205 (1934). The *Moore* case was brought in federal court by an employee of the defendant alleging injuries sustained in the defendant's railroad yard in Kentucky. The first count alleged injuries incurred in interstate commerce and was brought under the Federal Employers' Liability Act and Federal Safety Appliance Acts. The second count alleged that the injuries were received in intrastate commerce and cited the Federal Safety Appliance Acts for claims brought under the Employers' Liability Act of Kentucky.

In the second count, *Moore* alleged diversity of citizenship. At the time he filed suit, the venue statutes provided that a suit founded solely on diversity of citizenship could be brought in either the plaintiff's or defendant's place of residence, whereas a suit founded, solely or in part, on the existence of federal question jurisdiction could be brought only in the defendant's place of residence. Based on these venue restrictions, the defendant objected to the jurisdiction of the district court as to each count. The district court rejected defendant's objections and entered judgment for the plaintiff. On appeal, the court of appeals reversed, holding that the district court did not have jurisdiction to hear either count. The court of appeals, in reaching its opinion, reasoned that the second count attempted to set forth a claim under the Safety Appliance Acts and concluded that jurisdiction was not based solely on diversity of citizenship.

On review, the threshold issue faced by this Court was to determine whether plaintiff's counts presented a federal issue sufficient to confer federal question jurisdiction. The Court reasoned that under the Federal Employers' Lia-

bility Act, an employee has a private right of action for violation of the Safety Appliance Acts and held that the first count set forth a federal cause of action. As to the second count, the Court stated:

While invoking, in the second count, the Safety Appliance Acts, petitioner fully set forth and relied upon the laws of the state of Kentucky where the cause of action arose. . . . The Kentucky act provided that no employee should be held "to have assumed the risk of his employment" in any case "where the violation by such common carrier of any statute, State or Federal, enacted for the safety of employees contributed to the injury or death of such employee."

\* \* \*

Questions arising in actions in state courts to recover for injuries sustained by employees in intrastate commerce and relating to the scope or construction of the Federal Safety Appliance Acts are, of course, federal questions which may appropriately be reviewed in this Court. . . . But it does not follow that a suit brought under the state statute which defines liability to employees who are injured while engaged in intrastate commerce, and brings within the purview of the statute a breach of the duty imposed by the federal statute, should be regarded as a suit arising under the laws of the United States and cognizable in the federal court in the absence of diversity of citizenship. The Federal Safety Appliance Acts, while prescribing absolute duties, and thus creating correlative rights in favor of injured employees, did not attempt to lay down rules governing actions for enforcing these rights.

\* \* \*

The Safety Appliance Acts having prescribed the duty in this fashion, the right to recover damages

sustained by the injured employee through the breach of duty sprang from the principle of the common law . . . and was left to be enforced accordingly . . . .

*Id.* at 212-215 (citations omitted) (emphasis added).

While in *Moore* the ultimate issue concerned venue, to reach that issue, it was necessary for the Court to determine whether a state law claim invoking a federal safety act was cognizable in federal court in the absence of diversity of citizenship. The Court recognized that such claims present an issue of federal law but did not deem the federal issue sufficient to warrant primary adjudication in the federal courts. As the Court's discussion indicates, the availability of review by this Court on *certiorari* is sufficient to protect the federal interest involved. The underlying premise of the Court's analysis was that the effect of the federal statute in the resolution of the state claim is determined by state law. Therefore, the interests of the state in adjudicating the claim overshadows the federal interest involved.

This premise was applied and fully explained in *Jacobson v. New York, N.H. & H.R. Co.*, 206 F.2d 153, *aff'd per curiam*, 347 U.S. 909 (1954). The action was filed in federal district court alleging wrongful death resulting from injuries incurred while the decedent was a passenger on the defendant's train. The amended complaint alleged jurisdiction based on the existence of a question under the Safety Appliance Acts, 45 U.S.C. §1, *et seq.* In support of federal question jurisdiction, it was alleged that decedent's death was caused by defendant's negligent maintenance and operation of the brakes and couplings in violation of the provisions of the federal statute. On review of the district court's dismissal for lack of subject matter jurisdiction, the First Circuit held that the cause of action invoking the Safety Appliance Acts was not within the jurisdiction of the court under 28 U.S.C. § 1331.

The First Circuit noted that although Congress did not create a statutory right of action in favor of passengers

injured as a result of violations of the Safety Appliance Acts, the courts may create a right of action on the principles of the common law by regarding the breach of a penal statute as an operative fact on which common law tort liability may be predicated. The court then discussed the various common law principles developed by the states:

The courts of the various states differ extensively in their formulation and application of the common law principle upon which a liability is created in favor of a person injured by breach of a criminal statute. Some courts speak of the breach as "negligence *per se*", others as "evidence of negligence" or as "prima facie evidence of negligence." Nor are they completely in agreement as to what is meant by these phrases. Furthermore, liability in such cases is fitted into whatever local variations there may be in common law doctrines as to contributory negligence, last clear chance, assumption of risk, proximate cause, etc.

*Id.* at 156. The court further stated:

If the federal courts had undertaken to apply this [common law] principle as a matter of federal decisional law, in the case of a breach of the Safety Appliance Acts resulting in personal injury to a person not entitled to sue under the Employers' Liability Acts, and if such liability had been imposed as a matter of federal common law without reference to local variation of statutory law or of common law doctrine applicable in the state where the injury occurred, it would perhaps follow that a complaint setting up such a liability would be a civil action arising "under the Constitution, laws or treaties of the United States" within the meaning of 28 U.S.C. § 1331.

*Id.* at 157. The court noted that it is "abundantly clear that the courts have not, as a matter of federal common law, developed a private right of action for damages" for

passengers injured as a result of violations of the Safety Appliance Acts. The court concluded that if a passenger brought an action in state court for injuries resulting from a breach of the Acts, "issues bearing upon the right to recovery, relating, for example, to common law doctrines of last clear chance, the defense of contributory negligence, or proximate cause, depend upon the local law of the state." *Id.* at 157.

The holdings in *Moore* and *Jacobson* are not, as Petitioner asserts, based exclusively on the Holmes premise that "a suit arises under the law that creates the cause of action." *American Well Works Co. v. Layne & Bowler Co.*, 241 U.S. 257, 260 (1916). As the *Jacobson* opinion reveals, the rationale underlying these holdings is not susceptible to such categorical reduction. The First Circuit's examination of the state issues involved in a state law negligence claim based on violation of a federal penal statute demonstrates that the state issues inherent in such a claim predominate over the apparent federal issue. Stated in terms of policy, the interest of the state in resolving such claims outweighs the federal interest.

In *Crane v. Cedar Rapids & Iowa City Railway Co.*, 395 U.S. 164 (1969), the Court discussed the relationship between state law theories of negligence and violation of a federal safety statute. The case, which was brought in state court, was reviewed by this Court on *certiorari* to the state supreme court. The issue before the Court was whether a state may make the defense of contributory negligence available to a railroad sued by a nonemployee for injuries caused by the railroad's failure to maintain its freight cars in accordance with the provisions of the Safety Appliance Acts, 45 U.S.C. § 2. The Court determined that the present federal statutory scheme does not create a federal cause of action for nonemployees injured as a result of violations of the Safety Appliance Acts. The Court thereafter stated:

[T]he nonemployee must look for his remedy to a common-law action in tort, which is to say that

he must sue in a state court, in the absence of diversity, to implement a state cause of action. . . . "[T]he right to recover damages sustained . . . through the breach of duty sprang from the principle of the common law . . . and was left to be enforced accordingly. . . ." In consequence, we have consistently held that under the present statutory scheme the definition of causation and the availability of the defenses of assumption of risk and contributory negligence are left to state law.

*Id.* at 166-167 (emphasis added) (citations omitted).

*Crane* did not involve the issue of federal jurisdiction. However, the holding is relevant to the issues before this Court. In *Crane*, the Court recognized that the states have a significant interest in litigating claims alleging negligence based on violation of a federal safety statute. When no federal right of action exists, issues bearing on the plaintiff's right to recover on such claims are important state concerns which should be left to be enforced by the states.

Lower federal courts have overwhelmingly held that negligence claims based on violations of federal safety statutes should be heard in state court. In *Andersen v. Bingham & G. Ry. Co.*, 169 F.2d 328 (10th Cir. 1948), the district court remanded a case alleging a violation of the Safety Appliance Acts, 45 U.S.C. § 1, *et seq.*, as one of ten separate grounds of negligence. The court stated that the allegation merely tendered an issue of fact as to whether the requirements of the Acts were violated. *Id.* at 330. In *Dennis v. Southeastern Aviation, Inc.*, 176 F.Supp. 542 (1959), the plaintiff alleged violations of the rules and regulations of the Federal Civil Aeronautics Act. The district court remanded the case on the ground that the allegation simply tendered another issue of negligence. *Id.* at 254.

Lower courts considering allegations of violation of the FDCA in actions brought by private individuals have held

that the allegations do not create federal question jurisdiction and, therefore, must be heard in state court. In *Gelley v. Astra Pharmaceutical Products, Inc.*, 466 F.Supp. 182 (D.Minn. 1979), *aff'd*, 610 F.2d 558 (8th Cir. 1979), the court dismissed the plaintiff's action for lack of subject matter jurisdiction, stating:

This court . . . holds that the Food, Drug and Cosmetic Act does not, by implication, provide a monetary remedy to a private person injured as a result of a violation of the Act. *Cort v. Ash*, 422 U.S. 66, 75 S.Ct. 2080 (1975).

As there exists no private cause of action for a violation of the Act, there is no federal question jurisdiction. . . . As the parties are not diverse, it necessarily follows that this Action must be dismissed for lack of subject matter jurisdiction.

*Id.* at 187, *aff'd*, 610 F.2d 558 (citations omitted).

In *State of Florida ex rel. Broward County v. Eli Lilly & Co.*, 329 F.Supp. 364 (S.D.Fla. 1971), the state sued in federal district court on its own behalf, and on behalf of consumers who sought monetary damages under the FDCA. In dismissing the action on the ground that violations of the FDCA do not constitute an independent basis for federal question jurisdiction, the court stated:

There is no need to decide whether under Florida law violation of the [Federal Food, Drug and Cosmetic] Act constitutes negligence *per se*, for absent diversity, a complaint that alleges common law theories of recovery based upon the violation of a duty owed under a federal statute must be brought in State court.

*Id.* at 366 n. 3 (citations omitted).

As will be discussed in Point II of Respondents' Brief, Respondents' allegation that Petitioner misbranded Benadryl in violation of the FDCA does not present a novel federal question requiring the unique abilities of a federal

court. Therefore, their allegation is not distinguishable from the allegations considered in *Moore*, *Jacobson* or other decisions cited above.

**C. Allegations That Petitioner Violated Provisions Of The Food, Drug And Cosmetic Act Constitute A Response Made In Anticipation Of Defenses Petitioner May Assert And, Therefore, Do Not Give Rise To Federal Question Jurisdiction.**

The well-pleaded complaint rule provides a substantive test for determining whether Respondents' fourth causes of action "arise under" federal law within the meaning of 28 U.S.C. § 1331. The rule was set forth in *Taylor v. Anderson*, 234 U.S. 74 (1914), as follows:

[W]hether a case is one arising under the Constitution or a law or treaty of the United States in the sense of the jurisdictional statute . . . must be determined from what necessarily appears in the plaintiff's statement of his own claim, *unaided by anything alleged in anticipation of avoidance of defenses which it thought the defendant may interpose*.

*Id.* at 75-76 (emphasis added). The rule was recently expressed by the Court in *Franchise Tax Board*: "A federal court does not have original jurisdiction over a case in which the complaint presents a *state-law cause of action*, but also asserts that *federal law deprives the defendant of a defense he may raise*." 363 U.S. at 10 (emphasis added).

Allegations of violations of federal safety statutes in support of state law negligence claims, if established, will, on state common law principles, or by statutes, limit the defenses available to the defendant. The extent to which such allegations will burden the defense will depend on the law of the particular state.

The legal effect of violations of the FDCA in the instant case will be determined by the common law of Ohio. In Respondents' complaints, they allege that the violation of the federal statute constitutes "a rebuttable presumption

of negligence." J.A. 32. In Respondents' motion to remand, they point out that violation of a state or federal safety statute constitutes "negligence *per se* under Ohio law.<sup>4</sup> However, no matter how a violation of the federal statute functions in establishing negligence under Ohio law, a violation will *deprive the defendant of some defense he may raise*.

If violation of the federal safety statute is negligence *per se* under Ohio law, then a finding that the statute was violated will deprive Petitioner of any defenses to a claim of negligence available under Ohio law. If violation of the statute constitutes a rebuttable presumption of negligence, then a finding of a violation will shift the burden of proof to Petitioner, thereby foreclosing the defense that negligence was not shown by a preponderance of the evidence. If violation of the statute is considered only evidence of negligence, then a finding that the statute was violated will deprive Petitioner of the defense that it acted in conformity with the customs of the pharmaceutical industry and, hence, acted reasonably. Thus, at the very least, the allegation of violation of the statute is a response anticipating that Petitioner will assert that it met the standard of care of a reasonable drug manufacturer.

For the foregoing reasons, Respondents' fourth causes of action are state law causes of action in negligence which assert that federal law deprives the defendant of a defense he may raise and, therefore, do not vest original jurisdiction in the federal court.

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<sup>4</sup>Under Ohio law, violation of a specific safety statute is negligence *per se*, rendering the defendant liable if his negligence caused or contributed to causing the plaintiff's injury. *Shroades v. Rental Homes, Inc.*, 68 Ohio St. 2d 20, 427 N.E.2d 774 (1981); *Freeman v. United States*, 509 F.2d 626, 630 (6th Cir. 1975).

**II. WHERE A PRIVATE LITIGANT SEEKS A MONETARY REMEDY ON THE THEORY OF NEGLIGENCE AND ALLEGES, *INTER ALIA*, THAT A DRUG MANUFACTURER VIOLATED PROVISIONS OF THE FDCA, THE ALLEGATIONS DO NOT CREATE A FEDERAL INTEREST SUFFICIENT TO REQUIRE RESOLUTION BY A FEDERAL COURT.**

**A. State Applications Of Provisions Of The FDCA In Suits Involving Only Private Litigants Will Not Affect The Federal Scheme Regulating Pharmaceuticals.**

Section 307 of the Food, Drug and Cosmetic Act, 21 U.S.C. § 337, provides that "all" proceedings for the enforcement of the Act or to restrain violations of the Act "shall be by and in the name of the United States." Moreover, federal courts considering claims by private litigants for money damages or injunctive relief have uniformly refused to imply a private right of action under the Act on the ground that Congress expressly declined to provide one. *See National Women's Health Network, Inc. v. A.H. Robins, Inc.*, 545 F.Supp. 1177, 1179 (D.Mass. 1982)<sup>5</sup>. Therefore, a body of federal common law has not been developed to govern such claims.

Since Congress has established that the provisions of the FDCA are only to be enforced publicly, resolution of claims involving only private litigants by a federal court will not promote a significant federal interest. Moreover, resolution of the claims by the Ohio court will not burden the United States in the enforcement of the FDCA or frustrate the operations of the Food and Drug Administration.

In *Howard v. Group Hospital Service*, 739 F.2d 1508 (10th Cir. 1984), the court concluded that if state court resolution of a claim will not adversely affect a federal interest, federal question jurisdiction should not be in-

<sup>5</sup>See Hearings on S. 1944 (Subcommittee of Committee on Commerce), 73d Cong., 2d Sess.

voked. The *Howard* case was brought in state court for damages in tort and contract resulting from Blue Cross' failure to pay claims under a Federal Employee Health Benefit Program (FEP) on the basis that there was no medical necessity for the treatment. Blue Cross removed the case and the district court denied remand. Under 5 U.S.C. § 8901-13, the Office of Personnel Management (OPM) contracts for and approves health benefit plans covering federal employees, and the federal government subsidizes the subscription charge. Blue Cross, which had a contract with the OPM setting forth an approved plan, argued that federal law should apply to the interpretation of the contract. On review, the court of appeals stated:

[W]hen the federal government has an articulable interest in the outcome of a dispute, federal law governs. Thus, if diverse resolutions of a controversy would frustrate the operations of a federal program, conflict with a specific national policy, or have some direct effect on the United States or its treasury, then federal law applies. . . . We fail to see how various state court adjudications of FEP benefits claims will frustrate the operation of that program or conflict with a specific national policy.

*Id.* at 1510-1511 (citations omitted) (footnote omitted). On that premise, the court remanded the case, holding that the claim "is a private controversy in which the federal government simply does not have an interest sufficient to justify invoking federal question jurisdiction." *Id.* at 1512.

In determining the presence of federal question jurisdiction, the court in *Howard* relied heavily on *Miree v. DeKalb County*, 433 U.S. 25 (1977), in which petitioners brought actions, arising out of an air crash, in federal court. Their complaints alleged that they were third-party beneficiaries of grant contracts between the county and the Federal Aviation Administration, and that the county breached the contracts by maintaining a garbage dump adjacent to the airport that attracted birds and caused

them to be drawn into the jet engines. Although the claims were brought on the basis of diversity of citizenship, the court of appeals held that the application of federal law was required because the United States was a party to the contract. The Supreme Court reversed, based on the following rationale:

*While federal common law may govern even in diversity cases where a uniform national rule is necessary to further the interests of the federal government . . . , the application of federal common law to resolve the issue presented here would promote no federal interest. . . . [T]he resolution of petitioners' breach-of-contract claim against the respondent will have no direct effect upon the United States. . . . Since only the rights of private litigants are at issue here we find the Clearfield Trust rationale inapplicable.*

*Id.* at 29 (footnotes omitted) (emphasis added). The Court further stated:

In deciding whether rules of federal common law should be fashioned, normally the guiding principle is that a *significant conflict between some federal policy or interest and the use of state law in the premises must first be specifically shown.* . . . Whether latent federal power should be exercised to displace state law is primarily a decision for Congress.

*Id.* at 31-32, quoting *Wallis v. Pan American Petroleum Corp.*, 384 U.S. 63, 68 (1966) (emphasis added).

When state law brings a federal safety statute within its scope, the state law, in effect, points to the federal statute as establishing a standard of care. Thus, in the subject actions, the provisions of the Federal Food, Drug and Cosmetic Act function as a criterion for determining whether Petitioner has satisfied the duty of care prescribed by Ohio's common law theory of negligence. State law application of specific provisions of the Federal Food, Drug and Cosmetic Act in disputes involving only private litigants

will not frustrate the operations of the Federal Food and Drug Administration. As will be shown in the following two sections, the allegations in Respondents' fourth causes of action rely on well-defined and straightforward provisions that can be applied by the Ohio court. Moreover, Respondents' foreign citizenship and extraterritorial ingestion of Bendectin (Debendox) are simply factual issues regarding whether Petitioner developed, tested, promoted, manufactured, or sold the drug products in Ohio or directed any of these activities from Ohio, as to which the parties do not agree. This disputed factual issue, moreover, does not bear on any question relating to the scope or construction of the FDCA.

1. **State courts routinely apply provisions of safety statutes like the Federal Food, Drug and Cosmetic Act under their power to decide the common law of their jurisdiction.**

State courts routinely are asked to decide whether a violation of a federal statute will be used to establish a standard of care from which it is negligence to deviate. In other words, in their function as exponents of the common law, courts in each jurisdiction continually must decide whether, and to what effect, a violation of a federal statute will be used to establish a standard of care for their jurisdiction. In reaching these decisions, however, the state court does not seek to set forth pronouncements on the function or effect of the statute in the federal regulatory system; rather, the court seeks only to determine whether the Act *should be applied to afford protection against the conduct of the defendant.* This Court, moreover, has long recognized that state courts can and are willing to properly apply federal law. *Commonwealth of Pennsylvania v. Nelson*, 377 Pa. 58, 104 A.2d 133 (1954), aff'd, 350 U.S. 881 (1955).

Indeed, there are few provisions of federal law as devoid of ambiguity and as fully explained as the misbranding regulations for the FDCA. See 21 C.F.R. § 201.1. For example, 21 C.F.R. § 201.57(g) sets forth in explicit detail what a drug manufacturer must disclose in its labeling to

avoid having its drug found to be misbranded (false and misleading). Similarly, 21 C.F.R. § 202.1(e)(6) describes in detail the type of advertisement that would be false and misleading and violative of section 502(n) of the FDCA. In fact, the regulatory scheme enunciated by these regulations is, in most instances, far clearer than the typical jury instructions on the issue of negligence we commonly ask jurors to apply to the facts of the negligence.<sup>6</sup> In effect, all the court must do is to command the jury to determine whether the particular regulations at issue have been violated and, if so, whether the plaintiff's injuries are of the type which the regulation intended to avoid. Of course, the court may, under this definition of negligence *per se*, direct a verdict for the plaintiff, but courts always have this power to direct verdicts when the evidence dictates that they do so. Directing a verdict, however, is not tantamount to engaging in legislative interpretation.

In this respect, the Court is asked to take judicial notice of the provisions of Ohio law, OHIO REV. CODE ANN. § 3715.01, *et seq.*, which are identical to the federal misbranding statutes under 21 U.S.C. § 352. *Newcomb v. Brennan*, 558 F.2d 825 (8th Cir. 1977), cert. den., 434 U.S. 968 (1977). In the instant case, the state court, in attempting to decide the applicability of the FDCA misbranding provisions, will be forced to factor into its calculus

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<sup>6</sup>Compare Civil Jury Instruction 5-1, "Negligence Defined," *Standardized Civil Jury Instructions for the District of Columbia*, Revised Edition ("Negligence is the failure to exercise ordinary care. This negligence is doing something a person using ordinary care would not do, or not doing something a person using ordinary care would do. Ordinary care means that caution, attention or skill a reasonable person would use under similar circumstances"), with 21 C.F.R. § 202.1(e)(6)(iv) ("An advertisement is false . . . or otherwise misleading . . . (iv) Contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated.")

the Ohio State Legislature's intention in passing legislation identical to that found in the FDCA. In other words, the focus is not on the implementation of the FDCA, but rather on whether the common law of the State of Ohio will adopt as a standard of care in a tort action provisions making the misbranding of drugs evidence of negligence *per se*.

**B. Respondents Seek Damages For Negligent Acts By The Petitioner That Occurred In The State Of Ohio.**

Petitioner's suggestion that Respondents seek extraterritorial application of the FDCA is without merit. Petitioner, in its argument, claims that the Bendectin ingested by the Respondents was manufactured overseas and consumed overseas and, therefore, reasons that any violations of American law in the development, testing, and marketing of Bendectin that occurred in Ohio cannot form the basis of liability for the overseas Respondents.

This approach fails to consider significant events that clearly demonstrate that operative facts of negligence surrounding the manufacture and distribution of Bendectin occurred in Ohio. Bendectin, in all of its formulations, was developed and tested in Ohio. Moreover, the marketing of Bendectin was directed from Ohio, as was its labeling and advertising. Animal and human testing also was done primarily in Ohio. Manufacture of at least some of the drug sold abroad also was performed in Ohio. Similarly, the sale of Bendectin throughout the world was directed from Ohio.

If Petitioner violated the FDCA in the development, testing or sale of Bendectin, Ohio has a paramount interest in regulating Petitioner's conduct. *Lake v. Richardson-Merrell*, 538 F.Supp. 262 (N.D.Ohio 1982). Petitioner's assertion that only a federal court can properly determine the appropriate standard of care required of a drug manufacturer in Ohio, therefore, is without merit.

**C. The Federal Interest In Resolving Respondents' Claims, Or Similar Claims, If Any, Is Not Sufficient To Warrant A Finding That Will Open The Federal Courts To Countless Claims Now Resolved by State Courts.**

Congress has created federal statutes regulating the activities of many industries that affect the national welfare.

If the Court holds that state law negligence claims alleging violations of the statutes create federal question jurisdiction, then every plaintiff suing a party subject to federal regulation upon the theory of negligence will have access to the federal courts. An artful pleader will be able to invoke federal jurisdiction merely by alleging a violation of a federal regulatory provision.

Moreover, it is arguable that cases brought in state court will be removable to federal court if the plaintiff fails to explicitly refer to an appropriate standard that has a federal source. This becomes more probable if the state has not enacted a similar statute of its own. In other words, if a plaintiff bases a negligence claim on allegations that identify specific safety precautions required under a particular federal statute without alleging violation of the statute, the claim would be removable on the ground that is was artfully pleaded to avoid federal jurisdiction.

The Court confronted a similar dilemma relating to state declaratory judgments in *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1 (1983). In the *Franchise Tax Board* case, the Court considered the issue of whether the doctrine of *Skelly Oil v. Phillips Petroleum Co.*, 339 U.S. 667 (1950), limits federal jurisdiction under §§ 1331 and 1441 when a question of federal law appears on the face of a well-pleaded complaint for a state-law declaratory judgment. In deciding the issue, the Court stated:

If federal district courts could take jurisdiction, either originally or by removal, of state declaratory judgment claims raising questions of federal law, without regard to the doctrine of *Skelly Oil*, the federal Declaratory Judgment Act—with the limitations of *Skelly Oil* read into it—would become a dead letter. For any case in which a state declaratory judgment action was available, litigants could get into federal court for a declaratory judgment despite our interpretation of § 2201, simply by pleading an adequate state claim for a declaration of federal law.

*Id.* at 18. In holding that federal courts do not have jurisdiction when a federal question is presented by a complaint for a state declaratory judgment, the Court noted:

It is not beyond the power of Congress to confer a right to a declaratory judgment in a case or controversy arising under federal law—within the meaning of the Constitution or of § 1333—without regard to *Skelly Oil's* particular application of the well-pleaded complaint rule.... At this point, any adjustment in the system that has evolved under the *Skelly Oil* rule must come from Congress.

*Id.* at 18 n. 17.

Congress has not created a private right of action under many of its regulatory statutes. When drafting the FDCA, however, Congress expressly determined that a judicial right of action under the Act was unnecessary because the states provide a private remedy. Various state courts, on the other hand, have chosen to apply federal safety statutes on common law principles and decide how they will function in establishing negligence in the particular jurisdiction. Moreover, this Court has held that state courts have the power to make these decisions. *Crane v. Cedar Rapids & Iowa City Railway Co.*, 395 U.S. 164, 167 (1969). To restrict the power of the state to hear state-created negligence claims because they involve a federal statute which grants no private remedies, will greatly increase the dockets of the federal courts without promoting a significant federal interest.

## CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be upheld without modification and the judgment of the district court reversed by this Court.

Respectfully submitted,

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